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August 3, 2020

VIA ECF

Honorable Tonianne J. Bongiovanni, U.S.M.J.
United States District Court for the District of New Jersey
Clarkson S. Fisher Federal Building & U.S. Courthouse
402 East State Street
Trenton, New Jersey 08608

CONFIDENTIAL - FILED UNDER SEAL

Re: *Bristol-Myers Squibb Company v. Dr. Reddy's Laboratories, Ltd., et al.*
Civil Action No. 3:19-cv-18686 (MAS-TJB)

Dear Judge Bongiovanni:

This firm, together with Kirkland & Ellis LLP, represents Plaintiff Bristol-Myers Squibb Company ("BMS") in connection with the above-referenced matter. BMS submits the following response to Defendants Dr. Reddy's Laboratories Ltd. and Dr. Reddy's Laboratories, Inc.'s (collectively "DRL") application pursuant to Local Patent Rule 3.7 for leave to amend its invalidity contentions for U.S. Patent No. 8,242,270, served on July 17, 2020. Dkt. 57. For the following reasons, Plaintiff respectfully requests that the Court deny DRL's motion.

I. Procedural Background

On February 25, 2020, DRL served its invalidity contentions regarding BMS' Patent No. 8,242,270 ("the '270 patent"). DRL alleged that claims 7, 8 and 9 of the '270 patent were invalid for lack of enablement, but did not make any argument under 35 U.S.C. §112 regarding claim 1. In the intervening four months, the parties began claim construction, during which time DRL never sought to supplement its contentions or even raise with BMS that it intended to do so. DRL provided its terms for construction on March 10, seeking a construction of the term "crystalline butanol solvate of the compound of formula (IV)" from claim 1 of the '270 patent. On May 15, the parties exchanged proposed claim constructions, as follows:

| Term | BMS Construction | DRL Construction |
|---|---|--|
| "crystalline butanol solvate of the compound of formula (IV)" | "plain meaning as understood by a person of ordinary skill in the art, i.e., a butanol solvate of dasatinib in a crystalline form." | "crystalline form of the compound of formula (IV) containing <i>n</i> -butanol where the <i>n</i> -butanol is in a fixed position in the crystal lattice structure." |

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The parties met and conferred on several occasions thereafter to discuss the parties' positions on claim construction to try to reach agreement on proposed constructions or compromise proposed constructions. At no point did DRL raise its new invalidity theory and its intention to seek leave to amend. On May 30, BMS proposed a compromise construction, "crystalline form of dasatinib having butanol in the crystal structure." DRL agreed to this construction, again without raising any issue about a new invalidity theory based on this compromise construction or any intention to seek leave to amend DRL's invalidity contentions. On June 15, 2020, the parties submitted the agreed upon claim construction with their Joint Claim Construction and Prehearing Statement submitted to the Court (Dkt. 56).

On June 29, *four months* after DRL served its invalidity contentions, DRL for the first time raised its intention to seek leave to amend its invalidity positions, based upon the parties' "agreed upon construction of the term 'crystalline butanol solvate of the compound of formula (IV)' in claim 1 of the '270 patent." Ex. A, Breen e-mail, June 29, 2020. DRL did not provide BMS with its actual proposed amended contentions, or why it believed its proposed amendment was timely or supported by good cause, until July 9.

The parties met and conferred on July 14, during which BMS explained that it did not believe DRL's application was timely or supported by good cause, and that an amendment at this juncture would be prejudicial to BMS. Counsel for BMS also asked numerous questions, including whether DRL knew there were different butanols as of the time of writing its invalidity contentions, why DRL didn't raise this argument in its February contentions under the understanding of an alternative construction, and why DRL did not raise this issue in any of the parties' claim construction negotiations. See Ex. B, Ross e-mail, July 15, 2020. DRL's counsel refused to answer any question, citing "work product." BMS explained its concern that DRL did not act in good faith when it negotiated the compromise claim construction with BMS without mentioning DRL's position that such a construction, in its view, gives rise to a new § 112 invalidity argument. BMS further explained that when parties stipulate to a claim construction for a term and jointly request that the Court enter such a construction it is understood that the parties are in agreement that there is written support in the patent for the Court to adopt the proposed claim construction. DRL did not offer any response other than its unsupported view that it had no obligation to provide BMS with its new § 112 contentions during claim construction. On the parties' call, DRL also acknowledged it had no case law support for its posture: that a *stipulated* construction provides good cause to amend a party's invalidity contentions. This has not changed.

II. ARGUMENT

A. Legal Standard Governing DRL's Application for Leave to Amend Contentions Under Local Patent Rule 3.7

DRL's present motion stands in contravention of the intent behind the Local Rules of this Court. Local Patent Rule 3.5(c) requires that "[n]ot more than 30 days after the initial

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Scheduling Conference, each party opposing an assertion of patent infringement shall provide to each party asserting patent infringement the written basis for its ‘Invalidity Contentions,’ for any patents referred to in the opposing party’s Paragraph IV Certification.” L. Pat. R. 3.5(c). Local Patent Rule 3.3(d) further requires that a party set forth the “grounds of invalidity based on ... enablement or written description” in their contentions. Local Patent Rule 3.7 emphasizes the importance of fulsome, complete, early disclosure. That rule provides that “[a]mendment of any contentions, disclosures, or other documents required to be filed or exchanged pursuant to these Local Patent Rules may be made only by order of the Court upon a timely application and showing of good cause.” L. Pat. R. 3.7 (emphasis in original).

The purpose behind this and the other disclosure obligations outlined in the Local Patent Rules is for the parties to understand, early on in a matter, the full landscape of their respective disputes. In the explanatory notes on the Court’s 2011 amendments, the Rules Committee explained that “[t]o help ensure that the spirit of the disclosure obligations is fully appreciated, the Committee recommended various rules requiring parties to disclose all materials that they intend to rely upon in connection with ... invalidity contentions.” As one court in this District said:

“The Local Patent Rules were promulgated to further the goal of full, timely discovery and provide all parties with adequate notice and information with which to litigate their cases. ... A second and equally important purpose of these rules is to require parties to crystallize their theories of the case early in litigation and to adhere to those theories once they have been disclosed. ... This is intended to prevent the shifting sands approach to claim construction.”

Merck Sharp & Dohme Corp. v. Sandoz, Inc., No. 12–3289, 2014 WL 997532, at *3 (D.N.J. Jan. 6, 2014) (quotation marks and citations omitted). “The cornerstone of a motion to amend invalidity contentions is good cause,” and “[t]he key and primary consideration in determining the existence of good cause is the diligence of the moving party.” *Id.* at *7. In seeking leave to amend contentions, “[t]he burden is on the movant to establish diligence rather than on the opposing party to establish a lack of diligence.” *O2 Micro Int’l Ltd. v. Monolithic Power Sys., Inc.*, 467 F.3d 1355, 1366 (Fed. Cir. 2006) (considering similar patent rules in the Northern District of California, holding “[i]f the parties were not required to amend their contentions promptly after discovering new information, the contentions requirement would be virtually meaningless as a mechanism for shaping the conduct of discovery and trial preparation.”).

B. DRL Has Not Shown Good Cause for Amending Its Invalidity Contentions

DRL has not shown good cause in its motion. DRL’s invalidity contentions—including any contention as to non-enablement or lack of written description—were due in February. In its February 2020 submission, DRL specifically stated that “DRL’s invalidity contentions

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disclosed herein may reflect alternative claim constructions or invalidity theories.” Ex. C¹, at 3. DRL furthermore was able to come up with invalidity theories (that BMS disagrees with) under 35 U.S.C. §112 for other claims, based on potential alternative constructions, in their February contentions. Ex. C, at 21-23 (providing non-enablement argument for claims 7-9 of the ’270 patent); Ex. D, DRL’s Disclosure of Terms for Construction (seeking a definition of “crystalline compound of formula (IV)” from claims 7-9 of the ’270 patent). DRL has provided *no reason* why they could not have done the same for the argument they are now trying to add. Indeed, the argument raised in DRL’s original contentions is nearly the same as the non-enablement and written description argument they now seek to add:

| Non-enablement Theory from February Contentions | New Non-enablement / Written Description Theory |
|--|---|
| “the specification only teaches a person of ordinary skill in the art how to make a crystalline neat (N-6) form of the compound of formula (IV) having the claimed 2θ values.” | “the specification only teaches a person of ordinary skill in the art how to make a butanol solvate of the compound of formula (IV) using <i>n</i> -butanol.” |

This alone establishes that DRL’s application is untimely and DRL failed to act with diligence.

Moreover, DRL’s new proposed contentions are entirely based on the examples of the ’270 patent, which have been available to DRL since the beginning of this case (if not earlier). There has therefore been no change in circumstances; the patent has not changed, and no new evidence has come to light. As the court explained in *Pac. Bioscience. Labs., Inc. v. Nutra Luxe MD, LLC*, No. C10-0230, 2012 WL 12845608, at *3 (W.D. Wash. July 9, 2012), “a determination of enablement is an objective test—whether a person skilled in the art, ‘after reading the specification, could practice the claimed invention without undue experimentation’.” There, the defendant sought to amend its invalidity contentions to add a non-enablement theory after a Markman ruling. *Id.* The court denied this request, noting that the defendant was aware of the specification “since the beginning of this litigation, and therefore before it served its preliminary invalidity contentions.” *Id.* Likewise, DRL has been aware of the specification and its disclosures since before it served its invalidity contentions in February. That DRL only belatedly thought to extend its non-enablement theory from claims 7, 8 and 9 to claim 1 is no reason to grant the requested relief.

DRL relies upon an example from Local Patent Rule 3.7 that may provide good cause for an amendment where there is “(a) a claim construction by the Court different from that proposed by the party seeking amendment,” and cites to *Celgene Corp. v. Natco Pharma Ltd.*, No. 10-5197, 2015 WL 4138982, at *1-2 (D.N.J. July 9, 2015) for the proposition that good cause may be shown “when a term is construed differently from what a party proposed.” Mot. at 2. Neither the quoted portion of the Rule, nor the holding in *Celgene* support DRL’s request.

¹ Prior to filing its motion, DRL provided BMS with a copy of its intended amendments to its invalidity contentions. See Ex. C.

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First, the Rule's example is directed to claim constructions *by the Court*, not *stipulated* claim constructions voluntarily entered into by the party seeking amendment. DRL has failed to cite any authority in which a Court granted a motion to amend when the parties' *stipulated* claim construction was the basis for "good cause". To the contrary, at least one court in a jurisdiction with similar Local Patent Rules has considered this issue, and has determined that a moving party cannot be "surprised" by the court's adoption of a stipulated construction, and therefore denied a motion to amend sought on such grounds. *See* Ex. E, *Saffran v. Boston Sci. Corp.*, No. 05-cv-547, Dkt. 143 at 6 (E.D. Tex. 2008) ("BSC suggest [sic] that it was 'surprised' by the court's adoption of the parties' agreed construction....BSC could hardly be caught off-guard by a construction it advocated").

Second, DRL over-expands the holding in *Celgene*. In that case, the court relied on the provision in Local Patent Rule 3.7 that "a *claim construction by the Court* different from that proposed by the party seeking amendment" "*may*, absent undue prejudice to the adverse party, support a finding of good cause." *Celgene*, 2015 WL 4138982, at *3 (emphasis added). The Court has not entered its own claim construction here. Rather, DRL *chose* the meaning of "crystalline butanol solvate of the compound of formula (IV)." *Celgene* is therefore inapposite.

Moreover, even "a Markman *ruling* is not a 'free pass' to grant motions to amend contentions. The moving party still has to show that it acted diligently." Ex. F, *Horizon Pharma AG v. Watson Labs., Inc.—FL*, No. 13–5124, Dkt. 138 at 14 (D.N.J. Feb. 24, 2015) (emphasis added). DRL has not been diligent in seeking the requested amendment. At minimum, DRL has been aware of the potential for a construction of "crystalline butanol solvate of the compound of formula (IV)" that was broader than what it proposed since March 10, when DRL submitted this term for construction. Having raised the term for claim construction (only two weeks after it submitted its invalidity contentions), DRL must have been aware that a broader construction was possible. The good cause showing "requires diligence throughout the discovery process and that the moving party not only must act promptly upon discovery of new [information] but also must establish that it was diligent in its search." Ex. G, *Prometheus Labs. Inc. v. Roxane Labs., Inc.*, No. 11-cv-1241, Dkt. 174 at 13 (D.N.J. Aug. 6, 2012). Contrary to what DRL contends, it apparently *avoided* conducting a diligent analysis of the potential constructions for the term that it proposed, waiting nearly four months to act. On this basis alone, DRL's motion should be denied.

DRL also did not act when BMS proposed that the term be given its plain and ordinary meaning "i.e., a butanol solvate of dasatinib in a crystalline form." on May 15. This construction is clearly broader than the construction DRL proposed, the latter limiting the scope to only "*n*-butanol" solvates. Again, DRL could have moved to amend its invalidity contentions at this point, but did not. *See* Ex. G, *Prometheus Labs*, Dkt. 174 at 18 (holding "Defendant, accordingly, had a duty to formulate any invalidity defenses directed at plaintiff's proposed constructions as soon as it received them and promptly seek to amend contentions it wanted to have the ability to pursue."). Over the course of the subsequent four weeks, the parties engaged in at least two telephonic meet and confers, and sent numerous correspondence to one another. DRL still has not explained why it did not raise its invalidity theory to BMS at any

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point during the parties' negotiations. This sort of tactic is exactly what the Local Patent Rules seek to avoid: "[a]mendments to infringement and invalidity contentions are not granted as liberally as requests for amendments to pleadings in part because the philosophy behind amending claim charts is decidedly conservative and designed to prevent the 'shifting sands' approach to a party's contentions." Ex. G, *Prometheus Labs*, Dkt. 174 at 12 (internal quotations omitted). Because DRL failed to move to amend its contentions until *after* the parties had come to an agreement, demonstrating a lack of good faith and diligence, DRL's motion should be denied.

DRL tries to frame its "diligence" in terms of the period between when the Joint Claim Construction and Prehearing Statement was filed and when it notified BMS of its intention to amend its contentions. Mot. at 2. DRL focuses on the wrong time point. A defendant's "diligence is measured from the time within which they should have uncovered the information at issue." *Warner Chilcott Co. v. Mylan Inc.*, No. 13-6560, 2015 WL 3630970, at *7 (D.N.J. June 10, 2015); Ex. G, *Prometheus Labs*, Dkt. 174 at 20 ("the Court must look to the period of time between [when] the defendant learned of the basis of its amendment and the time it filed its application"). As explained above, DRL should have uncovered the basis for its new invalidity theories even *before* its February invalidity contentions were due. Yet DRL inexplicably waited *months* to raise its motion to amend. DRL has not shown diligence in moving to amend.

Even using the timeline from the case law that DRL cites, DRL has not been diligent. In *T.F.H. Publ'ns, Inc. v. Doskocil Mfg. Co.*, 705 F. Supp. 2d 361 (D.N.J. 2010), the court analyzed the movant's diligence from the period between when the party's *contentions* were filed, and when the party provided opposing counsel with the intended amendment. *Id.* at 363-64. Based on that court's analysis, DRL's invalidity contentions were served February 25, but it did not provide notice of its intent to amend its contentions until June 29, and waited until July 9 to provide a draft of its amendment. DRL's four-month delay, particularly in view of evidence that DRL was put on notice of the claim construction issue several times within that space, does not demonstrate diligence. See Ex. G, *Prometheus Labs*, Dkt. 174 at 21 (holding delay of "months before filing a request to amend" "fails to meet the local patent rules timely application requirement"). As such, DRL's motion should be denied.

C. DRL's Proposed Amendment Will Prejudice BMS

A moving party has the burden of establishing its application for leave to amend is both timely and supported by good cause *before* the question of prejudice even becomes relevant. *O2 Micro.*, 467 F.3d at 1368 ("[h]aving concluded that the district court could properly conclude that O2 Micro did not act diligently in moving to amend its infringement contentions, we see no need to consider the question of prejudice to MPS"); *Merck*, 2014 WL 997532, at *4 ("the Court will only consider prejudice to the non-moving party if the moving party has made the requisite showing of diligence"); *Warner Chilcott*, 2015 WL 3630970, at *6 ("Importantly, absent a showing of diligence, the Court does not reach prejudice"). BMS respectfully submits that the Court need to reach the issue of prejudice because DRL has not established that its application is timely and supported by good cause.

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DRL's deceptive practices in connection with claim construction and this subsequent application for leave to amend based on the parties' agreed upon proposed claim construction prejudice BMS. Had the parties not agreed to the construction now at issue, the Court would have had to consider DRL's arguments in support of its original construction (which limited the term to use of *n*-butanol as a solvate), including its likely argument, as set forth in its new contentions, that "the specification only teaches a person of ordinary skill in the art how to make a butanol solvate of the compound of formula (IV) using *n*-butanol." Ex. C at 23. By agreeing to a more expansive construction—in line with BMS' original construction, which did not limit the scope of the claim to only *n*-butanol solvates—DRL signaled to BMS that it was foregoing such arguments, and that the intrinsic evidence of the '270 patent supports the construction. For DRL to improperly resurrect such arguments *after* stipulating to the current construction constitutes unfair surprise and prejudice to BMS.

DRL's proposed amendment furthermore indicates it is a "supplemental explanation of *indefiniteness*, lack of written description, and/or lack of enablement." Ex. C at 23 (emphasis added). While the actual text of the proposed amendment only provides theories under the guise of lack of written description and enablement, to the extent DRL also seeks to add a theory of indefiniteness (without explanation), any such contention will unduly prejudice BMS. In essence, DRL would be arguing that a term that the parties agreed *has* a definite meaning is still somehow *indefinite*. "[A party] cannot prejudice an opposing party by unexpectedly reasserting an indefiniteness argument that was not previously or consistently raised and after stipulating to claim construction." *BioCell Tech. LLC v. Arthro-7*, No. 12-00516, 2013 WL 12131282, at *9 (C.D. Cal. April 16, 2013).

* * *

For the above reasons, BMS respectfully requests that the court deny DRL's application for leave to amend DRL's invalidity contentions for the '270 patent. Should Your Honor or Your Honor's staff have any questions regarding BMS' opposition, we are always available.

Respectfully submitted,

s/Liza M. Walsh

Liza M. Walsh

cc: All Counsel of Record (via ECF and e-mail)

EXHIBIT A

From: [Breen, James](#)
To: [#BMSDasatinibLitigation](#); [Ben-Arri, Leora](#); [Christine Gannon](#); [Jagoe, Christopher T.](#); [Liza Walsh](#); [Mary Hogan](#); [Wacker, Jeanna](#); [Ilardi, Chris T.](#); [Ross, Ashley](#)
Cc: [DG-DASATINIB](#); [Valenti, Alexandra D](#); [Blais, Elaine Herrmann](#); [Frederickson III, Robert](#); [aeckenthal@lernerdavid.com](#); [*wmentlik@lernerdavid.com](#); [Flaccavento, Donna M.](#)
Subject: 3:19-cv-18686-MAS-TJB BRISTOL-MYERS SQUIBB COMPANY v. DR. REDDYS
Date: Monday, June 29, 2020 6:21:13 PM
Attachments: [image001.png](#)



Counsel,

In light of the agreed upon construction of the term “crystalline butanol solvate of the compound of formula (IV)” in claim 1 of the ’270 patent, DRL intends to seek leave from the court to amend its invalidity positions to include arguments under 35 U.S.C. § 112.

Please let us know if BMS consents to this amendment. We are available to discuss.

Regards,
James

James Breen



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EXHIBIT B

Parrado, Alvaro

From: Ross, Ashley
Sent: Wednesday, July 15, 2020 12:33 PM
To: Valenti, Alexandra D
Cc: DG-DASATINIB; Breen, James; #BMSDasatinibLitigation; Ben-Ami, Leora; Christine Gannon; Jagoe, Christopher T.; Liza Walsh; Mary Hogan; Wacker, Jeanna; Ilardi, Chris T.; Blais, Elaine Herrmann; Flaccavento, Donna M.; Frederickson III, Robert; *wmentlik@lernerdavid.com; aeckenthal@lernerdavid.com
Subject: RE: 3:19-cv-18686-MAS-TJB BRISTOL-MYERS SQUIBB COMPANY v. DR. REDDYS LABORATORIES, LTD. et al

Alex,

I write to memorialize our meet and confer yesterday. To the extent your understanding of our call differs from any aspect of the below, please immediately let us know.

REDACTED

DRL's Request to Amend its Invalidity Contentions

I reiterated that DRL's newest invalidity theory is not currently in the case, and that DRL had failed to show good cause for why it should be permitted to amend its contentions at this juncture. I asked you several questions, none of which you substantively answered (citing "work product"), including whether you knew there were different butanols as of the time of writing DRL's invalidity contentions, why DRL didn't raise this argument in its February contentions under the understanding of an alternative construction, and why DRL did not raise this issue in any of the parties' claim construction negotiations. I further requested any case law that supports DRL's request (in particular, where the parties have *stipulated* to a construction, prompting one party to move to amend its invalidity contentions). You indicated that DRL has not yet provided any such support, but that if DRL decides to move on this issue, you will provide us with your supportive cases and notify us of your intent to go to the Court.

Regards,

Ashley

Ashley Ross

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ashley.ross@kirkland.com

From: Breen, James <JamesBreen@goodwinlaw.com>

Sent: Tuesday, July 14, 2020 10:17 AM

To: Ross, Ashley <ashley.ross@kirkland.com>

Cc: Valenti, Alexandra D <AValenti@goodwinlaw.com>; DG-DASATINIB <DG-DASATINIB@goodwinlaw.com>; #BMSDasatinibLitigation <BMSDasatinibLitigation@kirkland.com>; Ben-Ami, Leora <leora.benami@kirkland.com>; Christine Gannon <CGannon@walsh.law>; Jagoe, Christopher T. <christopher.jagoe@kirkland.com>; Liza Walsh <LWalsh@walsh.law>; Mary Hogan <MHogan@walsh.law>; Wacker, Jeanna <jeanna.wacker@kirkland.com>; Ilardi, Chris T. <chris.ilardi@kirkland.com>; Blais, Elaine Herrmann <EBlais@goodwinlaw.com>; Flaccavento, Donna M. <dflaccavento@lernerdavid.com>; Frederickson III, Robert <RFrederickson@goodwinlaw.com>; *wmentlik@lernerdavid.com <wmentlik@lernerdavid.com>; aeckenthal@lernerdavid.com

Subject: RE: 3:19-cv-18686-MAS-TJB BRISTOL-MYERS SQUIBB COMPANY v. DR. REDDYS LABORATORIES, LTD. et al



> This message is from an EXTERNAL SENDER - be cautious, particularly with links and attachments.

Ashley,

We are available today at 4pm EST to discuss REDACTED proposed invalidity contention amendment. Please be prepared to meet and confer on both topics.

DRL's

Regards,

James

James Breen



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From: Ross, Ashley <ashley.ross@kirkland.com>

Sent: Monday, July 13, 2020 3:09 PM

To: Breen, James <JamesBreen@goodwinlaw.com>

Cc: Valenti, Alexandra D <AValenti@goodwinlaw.com>; DG-DASATINIB <DG-DASATINIB@goodwinlaw.com>; #BMSDasatinibLitigation <BMSDasatinibLitigation@kirkland.com>; Ben-Ami, Leora <leora.benami@kirkland.com>; Christine Gannon <CGannon@walsh.law>; Jagoe, Christopher T. <christopher.jagoe@kirkland.com>; Liza Walsh <LWalsh@walsh.law>; Mary Hogan <MHogan@walsh.law>; Wacker, Jeanna <jeanna.wacker@kirkland.com>; Ilardi, Chris T. <chris.ilardi@kirkland.com>; Blais, Elaine Herrmann <EBlais@goodwinlaw.com>; Flaccavento, Donna M. <dflaccavento@lernerdavid.com>; Frederickson III, Robert <RFrederickson@goodwinlaw.com>; wmentlik@lernerdavid.com; aeckenthal@lernerdavid.com

Subject: RE: 3:19-cv-18686-MAS-TJB BRISTOL-MYERS SQUIBB COMPANY v. DR. REDDYS LABORATORIES, LTD. et al

James,

EXHIBIT C
REDACTED IN
ITS ENTIRETY

EXHIBIT D



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March 10, 2020

VIA E-MAIL

Leora Ben-Ami
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Christopher T. Jagoe
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Liza M. Walsh
Christine I. Gannon
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Re: *Bristol-Myers Squibb Co. v. Dr. Reddy's Laboratories S.A., et al.*, Civ. A. No. 19-18686 (D.N.J.)

Dear Counsel:

Pursuant to the Scheduling Order entered in this matter (D.I. 24 at 2), Dr. Reddy's provides the following list of claim terms and phrases from U.S. Patent Nos. 7,491,725; 8,242,270; and 8,680,103 that it believes need to be construed. Dr. Reddy's reserves the right to supplement or amend this list after reviewing the claim terms and phrases that BMS provides.

| Asserted Claim(s) | Term |
|--|---|
| '725 patent, claims 1, 3, and 12 '103 patent, claim 1 | "crystalline monohydrate of the compound of formula (IV)" |
| '270 patent, claim 1 | "crystalline butanol solvate of the compound of formula (IV)" |
| '270 patent, claims 7-9 | "crystalline compound of formula (IV)" |



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| Asserted Claim(s) | Term |
|---|--|
| '103 patent, claims 2-4 | "wherein the compound of formula (IV)" |
| '725 patent, claim 3 '103 patent, claim 3 '270 patent, claims 7 and 9 | "an x-ray powder diffraction pattern . . . comprising four or more 2 θ values selected from the group consisting of" |
| '725 patent, claim 1 | "characterized by an x-ray powder diffraction pattern substantially in accordance with that shown in FIG. 1" |
| '725 patent, claim 2 '103 patent, claim 2 | "characterized by differential scanning calorimetry thermogram and a thermogravimetric analysis substantially in accordance with that shown in FIG. 2" |
| '725 patent, claims 13 and 14 | "therapeutically effective amount" |

Sincerely,

/s/ Alexandra D. Valenti

Alexandra D. Valenti

EXHIBIT E

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION**

BRUCE N. SAFFRAN, Ph.D., M.D.,
Plaintiff,

v.

BOSTON SCIENTIFIC CORPORATION.
Defendant.

§
§
§
§
§
§
§
§

CIVIL ACTION NO. 2-05-CV-547 (TJW)

ORDER

Before the court is Plaintiff's Motion to Strike Defendant's Amended Invalidity Contentions Allegedly Served Pursuant to Patent Rule 3-6(a)(2)(B) and Corresponding Portions of the Expert Report of Harold B. Hopfenberg (#89)(the "Motion to Strike") and the defendant's Motion for Leave to Amend (#107)("Motion for Leave").¹ For the following reasons, the Motion to Strike is GRANTED, and the Motion for Leave is DENIED.

I. BACKGROUND

Bruce N. Saffran, Ph.D., M.D., ("Saffran") filed this suit on December 16, 2005. Pursuant to the Local Rules, the defendant, Boston Scientific Corporation ("BSC") filed its Invalidity Contentions on December 4, 2006. The parties exchanged their claim construction positions on March 28, 2007 and submitted their joint claim construction and pre-hearing statement to the court on June 15, 2007. The court conducted a claim construction hearing on July 26, 2007. The court issued its claim construction order on September 28, 2007. Pursuant to the docket control order, opening expert witness reports were due on October 23, 2007, technical expert rebuttal reports were due on November 6, 2007, expert deposition discovery closed on December 20, 2007, and the

¹BSC drafted the Motion for Leave in the body of its opposition to the Motion to Strike.

deadline for identifying trial witnesses was November 20, 2007.² On November 16, 2007, approximately six weeks before the original date of jury selection, BSC served amended Invalidity Contentions. The new contentions form the basis for the Motion to Strike.

In its November 16, 2007 amendment, BSC modified its Invalidity Contentions in part as follows:³

1. BSC added the Lambert PCT Application.⁴
2. BSC added the 1994 Lambert Abstract.
3. BSC added the Ding Patent.
4. BSC added the “prior work” of Dr. Thomas L. Lambert and Dr. Vishva Dev.
5. BSC added the Dev abstract.
6. BSC added the Dev article.
7. BSC added the Lambert ‘246 Patent.
8. BSC added the theory that the ‘760 patent does not enable a combination to make a layer of flexible material that is minimally porous to macromolecules or a specific material to be used as the treating material.

²The court notes that the parties jointly asked for and received extensions for these specific dates.

³The court created this list using the summary of changes “made in BSC’s Amended Invalidity Contentions” provided by BSC to Saffran and attached as Exhibit 8 to the Motion to Strike (the “Chart”). The court’s summary is not exhaustive.

⁴For brevity, the court uses the abbreviations for prior art references that BSC used in its Amended Invalidity Contentions.

9. BSC added the theory that the ‘760 patent does not enable “us[ing] a hydrophobic drug and hydrophobic polymer to perform the function of ‘releasing a treating material toward the damaged tissue’ in a damaged blood vessel” or “a specific combination of a specific hydrophobic drug and a specific hydrophobic polymer.”

10. BSC added the theory that the ‘760 does not enable attaching a therapeutically effective amount of a treating material to a layer of material that is minimally porous to macromolecules.

11. BSC added the contention that Aebischer ‘486, Schwartz, Scott and the 1989 Aebischer article anticipate claim 9.

12. BSC added the contention that the asserted claims are indefinite if “chemical bonds and linkages” encompasses more than “chemical bonds.”

13. BSC added the contention the ‘760 patent is indefinite as it relates to the presence or absence of a “sheet,” “stents with large, uncovered gaps between the stent struts through which cells and macromolecules may pass,” and “a layer of flexible material that is minimally porous to macromolecules” or “evenly dispersed within a ‘layer of flexible material that is minimally porous to macromolecules.’”

BSC offered an explanation(s) for each amendment in the Chart. BSC seeks to justify its amendments by pointing to: (1) the court’s construction for the claim term “material release means;”

(2) its assertion that the additional prior art references provide only “additional information about a construction previously disclosed;” (3) the court’s construction for the claim term “small molecules;” (4) the court’s construction for the term “flexible fixation device;” (5) the court’s construction for the claim term “device;” and (6) the court’s construction for the claim term “minimally porous to macromolecules.”⁵

II. MOTION TO STRIKE

Saffran asks the court to strike BSC’s Amended Invalidity Contentions as well as the corresponding portions of Dr. Hopfenberg’s expert report. BSC argues that its amendments to the Invalidity Contentions were *necessitated* by the court’s *unexpected* claim constructions and that much of the information disclosed in the new prior art references is disclosed in the original Invalidity Contentions. BSC further argues that Saffran’s expert reports necessitated BSC’s amendments to its original Invalidity Contentions. These arguments are without merit and could be classified as frivolous. The amendments to the Invalidity Contentions are untimely, and the court strikes them as well as the corresponding portions of BSC’s expert report(s).

A. Unexpected Claim Constructions

First, the court addresses BSC’s argument that the court’s claim constructions were unexpected to such a degree that they forced BSC to amend its Invalidity Contentions. Local Patent Rule 3-6(a)(2)(B) permits a party to amend its invalidity contentions without leave of court within 50 days of the court’s claim construction order when the party believes in good faith that the court’s

⁵The parties submitted an agreed construction for the claim term “small molecules.” The court declined to construe the terms “flexible fixation device,” “device,” and minimally porous to macromolecules.”

claim construction so requires. The court emphasizes that the amending party must believe *in good faith* that the court's claim construction requires the amendment. BSC has not shown that it acted in good faith.

The purpose of requiring preliminary contentions is to “require the parties to crystallize their theories of the case early in litigation.” *Nike, Inc. v. Adidas America, Inc.*, 479 F.Supp.2d 664, 667 (E.D. Tex. 2007)(citing *02 Micro International Ltd. v. Monolithic Power Systems*, 476 F.3d 1355, 1364 (Fed. Cir. 2006)). A party is permitted to amend its contentions in response to an *unexpected* claim construction, not simply a construction with which the party disagrees. *See Nike, Inc.*, 479 F.Supp. 2d at 667-668 (emphasis added).

In the present case, the court issued its claim construction order on September 28, 2007. The court adopted the parties' agreed constructions for 4 terms, construed 4 terms,⁶ and held that the remaining disputed terms did not need construction. However, out of all of the claim term constructions BSC alleges necessitated the amendments, the only term construed by the court independent of the parties' agreement was “material release means.” BSC alleges that the court's construction of “small molecules” necessitated a belated amendment, but the court simply adopted the parties' *agreed* construction for that claim term. Finally, BSC maintains that the court's decision that the jury could ascertain the plain meaning of “flexible fixation device,” “device,” and “minimally porous to macromolecules”⁷ was so unexpected that BSC had to amend its invalidity contentions. These arguments are rejected and could be described as specious.

⁶The court found “directional” and “unidirectional” to be synonymous as used in claims 1, 8, and 15.

⁷The court construed the term “macromolecules.”

Here, the court's claim construction was foreseeable by BSC. BSC has known of Saffran's proposed claim construction for "material release means" since March 28, 2007, but it did not, however, seek to amend when it learned of that position. As noted in BSC's opposition brief, the court "essentially adopted Saffran's proposed structure for the material release means elements" and concluded that the identified structure was "chemical bonds and linkages." Opp. Brf. at 2. BSC cannot argue in good faith that the court's construction of "material release means" was unexpected in these circumstances. Even worse, BSC suggest that it was "surprised" by the court's adoption of the parties' agreed construction of "small molecules." BSC could hardly be caught off-guard by a construction it advocated. Finally, BSC has not explained, how, if at all, the court's decision not to construe the other claim terms justifies amending BSC's invalidity contentions.

BSC argues that Saffran cannot claim prejudice because it fully briefed the relevant motion(s) for summary judgment for invalidity, which include theories advanced by BSC in its Amended Invalidity Contentions. This argument asks the court to create an incentive for parties who improperly amend their contentions to file corresponding motions for summary judgment and to effectively punish parties for responding to motions for summary judgment. The court declines to facilitate improper conduct and rejects BSC's argument.

B. Saffran's Infringement Contentions

In addition, BSC argues that Saffran effectively amended its Infringement Contentions via its expert reports, particularly Dr. Freeman's expert report. BSC alleges that Dr. Freeman expanded the scope of the Infringement Contentions and that this justifies the amendments to the Invalidity Contentions.

The passage in particular to which BSC objects is:

Chemical bonds and linkages between paclitaxel and SIBS polymer (e.g., hydrophobic bonds, hydrogen bonds, and Pi-Pi bonds) serve to restrain paclitaxel in the SIBS layer until the layer is placed adjacent to damaged vascular tissue. . . The environment of the damaged tissue is more favorable to paclitaxel and therefore the chemical bonds and linkages between paclitaxel and SIBS are broken and paclitaxel is released toward the damaged tissue.

Freemen Report at 5/25.

The court rejects BSC's arguments. A cursory inspection of Saffran's Infringement Contentions shows that, while the expert report is more detailed, Saffran's Infringement Contentions encompass the passages objected to by BSC.

For instance, Saffran's Infringement Contentions state:

The Taxus product couples a hydrophobic polymer and a hydrophobic drug (paclitaxel). These hydrophobic materials interact to form a hydrophobic bond in the environment of the artery. . . Hydrophobic coupling retains the drug on the surface of the polymer layer so that the drug is delivered to the tissue, which contains hydrophobic binding sites.

Infringement Contentions at 6.

The chemical coupling between the hydrophobic polymer layer and the hydrophobic treating material is a type of chemical bond. This bond adheres the drug to the polymer until the polymer layer is placed next to the tissue. The layer then releases the treating material to the tissue.

Id. at 8.

. . . The polymer layer contains small pores within the polymer from which the drug elutes to the surface of the polymer. The drug is released from mechanical micropores and also from a chemical hydrophobic coupling on the tissue side of the device. . .

Id. at 7.

Saffran's Infringement Contentions encompass the cited passage of Dr. Freeman's opinion to which BSC objects. Accordingly, the court rejects BSC's argument that Saffran *de facto* amended

its Infringement Contentions via its expert report.

C. New Prior Art References

BSC added the following prior art references in its Amended Invalidity Contentions: Lambert ‘246, Ding, Lambert PCT, Dev Abstract, Dev Article, 1993 Lambert Abstract, 1994 Lambert Abstract and a collection of information that the parties refer to as the “work” of Dev and Lambert. In the Chart, BSC claims that it added these references in light of the court’s claim construction order. For the reasons previously mentioned, the court rejects the argument that BSC amended its Invalidity Contentions in good faith as a result of the court’s claim construction order.

BSC argues that it cured any prejudice to Saffran by belatedly adding Drs. Lambert and Dev to their trial witness list and making those witnesses available for deposition.⁸ This scenario is similar to the previously addressed addition of Invalidity Defenses. Here, BSC asks the court to allow it to improperly add prior art references to its Invalidity Contentions because it untimely identified witnesses on its trial witness list. Additionally, BSC uses the fact that Saffran declined to depose these belatedly identified “fact” witnesses less than six weeks from jury selection who have authored multiple papers and patents related to a subject that is intensely contested in this case to show that Saffran would suffer no prejudice. The court will not reward violating the Federal Rules of Civil Procedure and the Local Rules of this court.

Finally, BSC argues that the prior art references added in the Amended Invalidity Contentions simply are not “a new addition to BSC’s Invalidity Contentions.” Opp. Brf. at 8. The basis for this statement seems to be that an “article naming both Drs. Lambert and Dev as authors and a patent,

⁸ The court questions BSC’s intent to call Drs. Dev and Lambert only as fact witnesses as opposed to soliciting opinion testimony from them..

U.S. Patent No. 5,562,922, naming Dr. Lambert as the sole inventor, were included in BSC's original Invalidity Contentions." *Id.* The court does not agree with BSC's assessment. It does not follow that disclosing an article jointly authored by Drs. Dev and Lambert and a patent for which Dr. Lambert is the sole inventor means that a litany of other references disclose nothing new. Indeed, if that were the case, then it is not clear why BSC would have believed it necessary to list them in the Amended Invalidity Contentions. In short, BSC has offered no tenable argument for adding prior art references it knew, or should have known about, before the deadline for disclosing its Invalidity Contentions.

III. MOTION FOR LEAVE

BSC asks the court to grant it leave to add the Ding patent to its Invalidity Contentions. BSC owns the Ding patent and asserted it against Cordis in the U.S. District Court for the District of Delaware in 2003. On October 9, 2007, Saffran filed suit against Cordis and Johnson & Johnson accusing the Cypher Sirolimus-eluting Coronary Stent (the same stent found to infringe the Ding patent in Delaware) of infringing the '760 patent.

On October 23, 2007, BSC served Dr. Hopfenberg's expert report, which discussed the Ding patent "as it relates to the validity of the asserted claims of the '760 patent." Opp. Brf. At 13. Saffran's experts, Dr. Freeman and Dr. Jamison "discuss[ed] the Ding patent and/or respond[ed] to Dr. Hopfenberg's assertions regarding the validity of the '760 patent in light of Ding." *Id.* Of course, BSC uses this as evidence that Saffran will suffer no prejudice.

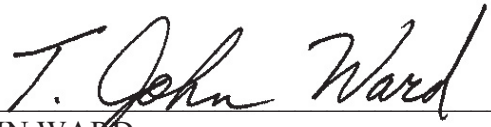
Once again, BSC offers the court no justifiable reason for the delay in disclosing a patent that BSC clearly knew about before October 23, 2007. BSC added the Ding patent in this case only after Saffran filed suit against Cordis and admits as much in its reply to Saffran's opposition to the Motion

for Leave. Specifically, BSC states in part that “[i]t was not until Saffran filed his complaint against Cordis on October 9, 2007 that BSC could make this argument.” Reply Brf. At 3. This argument is without merit. BSC had a duty to disclose the prior art upon which it sought to base its invalidity argument. Its conduct in failing to list the Ding patent is nothing if not consistent with its approach to the rest of its invalidity case. The court rejects its Motion for Leave.

IV. CONCLUSION

The court GRANTS the Motion to Strike and DENIES the Motion for Leave. The court rejects BSC’s arguments for amending its Invalidity Contentions. The court hereby strikes BSC’s Amended Invalidity Contentions and the corresponding portions of Dr. Hopfenberg’s expert reports.

SIGNED this 28th day of January, 2008.



T. JOHN WARD
UNITED STATES DISTRICT JUDGE

EXHIBIT F

[Doc. No. 114]

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

HORIZON PHARMA AG, et al.,
Plaintiffs,

v.

WATSON LABORATORIES, INC. -
FLORIDA, et al.,
Defendants.

Civil No. 13-5124 (JEI/JS)

MEMORANDUM OPINION AND ORDER

This matter is before the Court on defendant's "Motion Pursuant to L. Pat. R. 3.7 for Leave to Amend its Invalidity Contentions." [Doc. Nos. 114, 115].¹ The Court received plaintiffs' opposition [Doc. Nos. 123, 124] and defendant's reply [Doc. No. 129], and recently held oral argument. For the reasons to be discussed, defendant's motion is DENIED.

Background

By way of brief summary, plaintiffs filed this ANDA patent infringement lawsuit on August 26, 2013 alleging infringement of its '960, '407 and '124 patents. On January 13, 2014, the Court entered its initial Scheduling Order [Doc. No. 44] which mirrored the case management schedule set forth in New Jersey's Local Patent Rules. See L. Civ. R. 9.3. Pursuant to the Order

¹ The defendant is Actavis Laboratories FL, Inc. f/k/a Watson Pharmaceuticals, Inc. - Florida.

defendant served its invalidity contentions on January 21, 2014 and amended contentions (per the parties' consent and leave of court [Doc. No. 68]) on May 12, 2014. Thereafter, a Markman hearing was held on October 16, 2014 and the Markman Opinion and Order were issued on November 10, 2014. Pursuant to the current January 22, 2015 Amended Scheduling Order [Doc. No. 127], plaintiffs' expert reports are due to be served by February 27, 2015, responses are due by April 1, 2015, dispositive motions are due by June 22, 2015, and the Final Pretrial Conference is scheduled on September 10, 2015. The 30-month Hatch-Waxman stay of FDA approval of defendant's ANDA expires in January 2016.

Defendant's motion seeks leave to make three (3) amendments to its contentions. First, defendant seeks to add European Patent Application ("EP") '249 as a piece of prior art. Second, as to the '124 patent defendant seeks to assert a section 112 invalidity contention relating to indefiniteness. Three, as to the '124 and '407 patents defendant seeks to assert a Section 112 invalidity contention relating to lack of enablement. Defendant argues that EP '249 was not produced until September 11, 2014. Dr. Guy Vergnault, a Jagotec AG employee, is one of the named inventors of EP '249 as well as an inventor of the '124 and '407 patents. Dr. Vergnault was deposed on November 19 and 20, 2014. Defendant argues the "relevance and importance of [EP '249] was not clear until Dr. Vergnault's deposition."

Opening Brief ("OB") at 3. Defendant also argues that as a result of Dr. Vergnault's deposition it learned of a new indefiniteness contention involving the '124 patent as to a claim term construed in the November 10, 2014 Markman Opinion and Order. And defendant argues, it learned from Dr. Vergnault's deposition that the claims of the '124 and '407 patents are not enabled. Defendant insists it acted diligently and that plaintiffs will not be prejudiced by its amendments.

Not unexpectedly plaintiffs disagree with defendant. Plaintiffs argue defendant knew or should have known about EP '249 long ago. Plaintiffs point out that EP '249 is a published version of European Patent Application (Number 99114237.3) which was published a few days earlier as PCT '421. Opposition Brief ("OB") at 7.² Plaintiffs also point out that not only are the specifications of the PCT and EP publications identical (id.), but the PCT '421 reference appears on the face of the '124 and '407 patents. Plaintiffs argue, therefore, that "EP '249, in the form of PCT '421, was staring [defendant] in the face from the moment [defendant] first evaluated the '124 and '407 patents[.]" Id. at 8. As to defendant's argument that Dr. Vergnault's deposition testimony revealed for the first time the significance of EP '249, plaintiffs respond that this is

² Plaintiffs argue: "The newly relied upon EP '249 reference, and a PCT publication (WO 01/08421 A2, "PCT '421") that appears on the face of the patents-in-suit, are cognate publications by two different patent offices of the same European patent application." OB at 1.

nonsense. Plaintiffs argue that Dr. Vergnault "did little more than read the disclosure of the European Application Number 99114237.3 and confirm what it said." Id. at 11. Also, that defendant's failure to appreciate the materiality of the reference in the patents in suit (e.g., Application Number 9911427.3) "is purely a failure of [defendant] to fully read and study the reference." Id. at 12. As to the proposed indefiniteness amendment, plaintiffs argue all facts relevant to the new contention were known as early as June 2014. Id. at 15. As to defendant's enablement amendment, plaintiffs argue it is based on a misrepresentation of Dr. Vergnault's testimony.

Plaintiffs also argue that defendant's motion is late and they will be prejudiced by defendant's amendments. Plaintiffs argue their litigation strategy will change and it will "essentially go back to the drawing board." Also, that not only will new fact and expert discovery be needed but the litigation will be delayed, making it "impossible" to resolve the issues in dispute before the expiration of the 30-month stay in January 2016. Id. at 20.

Discussion

New Jersey L. Pat. R. 3.7 provides that contentions may only be amended upon Order of the Court "upon a timely application and showing of good cause." In O2 Micro Int'l Ltd. v. Monolithic Power Sys., Inc., 467 F.3d 1355, 1364-65 (Fed.

Cir. 2006), the Federal Circuit held that Federal Circuit law, not Circuit law, governs the interpretation of this Rule. Amendments to infringement and invalidity contentions are not granted as liberally as requests for amendments to pleadings. This is true in part because the philosophy behind amending claim charts is decidedly conservative and is designed to prevent the "shifting sands" approach to a party's contentions. King Pharmaceuticals Inc. v. Sandoz Inc., C.A. No. 08-5974 (GEB/DEA), 2010 WL 2015258 at *4 (D.N.J. May 20, 2010) (internal quotation marks and citations omitted).

The key factor courts look at to determine whether good cause exists to grant an amendment to a contention is the diligence of the moving party. The moving party, in this case defendant, has the burden of proof. O2 Micro, 467 F.3d at 1366. Diligence has two aspects to it. One is whether the moving party acted diligently to discover that a supplement or amendment was appropriate. The second aspect is whether the moving party promptly moved to amend its contentions after it learned an amendment was necessary. See generally O2 Micro, supra; AS America, Inc. v. Masco Corp. of Indiana, C.A. No. 13-05 (JBS/JS), 2013 WL 4084237, at *2 (D.N.J. Aug. 13, 2013). Other factors courts consider to determine whether good cause exists to grant an amendment are: (1) the reason for the delay, including whether it was within the reasonable control of the

party responsible for it; (2) the importance of what is to be excluded; (3) the danger of unfair prejudice; and (4) the availability of a continuance and the potential impact of a delay on judicial proceedings. LMT Mercer Group Inc. v. Me Ornamental, LLC, 2014 U.S. Dist. LEXIS 5719, at *17 (D.N.J. Jan. 16, 2014); see also Oy Ajat, Ltd. v. Vatech Amer., Inc., C.A. No. 10-4875 (PGS/DEA), 2012 WL 1067900, at *20 (D.N.J. March 29, 2012).

1. EP '249

As to EP '249, the Court has little trouble finding that defendant did not act diligently to discover that a supplement or amendment of its prior art was appropriate. After all, defendants acknowledge EP '249 is identical to PCT '421 which appears on the face of the '124 and '407 patents. If defendant exercised due diligence it would have known about the reference long ago. Indeed, defendant does not deny it knew about the PCT '421 reference.³ Defendant argues it did not previously identify EP '249 because it thought the reference was "cumulative" of its other references. Reply Brief ("RB") at 2. Defendant argues it was not until Dr. Vergnault's deposition that it realized the significance of the reference. The Court discounts defendant's argument for several reasons. First, defendant's argument is

³ As noted, plaintiffs argue that "Watson's failure to appreciate the materiality, if any, of the disclosure of the European Application Number 9911427.3 is purely a failure of Watson to fully read and study the reference." OB at 12.

new. If "cumulativeness" was the real reason for the non-inclusion it would have been raised in defendant's opening brief, not in defendant's reply brief. Defendant's opening brief focused on the fact that plaintiffs did not produce the 'EP 249 reference until September 11, 2014. It was only after plaintiffs pointed out in their reply brief that EP '249 and PCT '421 are identical that defendant made its "cumulativeness" argument. Second, in the Court's experience the fact that a piece of prior art is cumulative does not ordinarily deter parties from including the prior art in its contentions. Cumulativeness is not typically a party's paramount concern when it serves its contentions. The Court therefore questions the genuineness of defendant's "cumulative" argument. Third, there is no good explanation for why defendant waited so long to take Dr. Vergnault's deposition. Indeed, defendant has not even addressed the issue. Since EP '249 and PCT '421 were identical, and Dr. Vergnault's inventorship was known or should have been known at the outset of the case, defendant should have taken his deposition earlier. This would have avoided the present situation where defendant is seeking to amend its contentions after the fact discovery deadline expired, after claim construction, and on the eve of the production of plaintiffs'

expert reports.⁴ The timeliness of Dr. Vergnault's deposition is discussed in more detail infra.

In addition to finding that defendant did not act diligently to discover that a supplement or amendment was appropriate, the Court also finds that defendant did not move promptly to amend. Even if the Court credits defendant's argument that it was not until Dr. Vergnault's deposition on November 19 and 20, 2014 that it was alerted to the need to amend its prior art contention, defendant's motion was not filed until December 30, 2014. Given the late stage of the case and the expiration of the fact discovery deadline on December 19, 2014 (see January 13, 2014, Scheduling Order ¶ 19 [Doc. No. 44]), defendant should have acted with more urgency. See O2 Micro, 467 F. 3d at 1366 ("If the parties were not required to amend their contentions promptly after discovering new information, the contentions requirement would be virtually meaningless as a mechanism for shaping the conduct of discovery and trial

⁴ Defendant's argument that EP '249 is consistent with but not cumulative of its other prior art references is confounding. Reply Brief ("RB") 4. If, as defendant argues, the "disclosure of EP '249 is entirely consistent with the other references" (*id.* at 5), there is no need for an amendment. If the substance of the references are the same, but the EP '249 reference is merely "clearer and more focused" as defendant argues (*id.*), the references are cumulative. In any event, an amendment is not necessary since defendant's experts can presumably present their theories, in defendant's words, in a "clearer and more focused manner" without referring to EP '249. Indeed, even defendant minimizes the importance and necessity of EP '249. Brief at 2 ("EP '249 does not appear to be more relevant than the other art Actavis relied upon in its Invalidity Contentions."). See also RB at 9 ("[T]he disclosure of EP '249 is entirely consistent with the prior art previously disclosed[.]").

preparation.”). Defendant should not have waited six (6) weeks to file its motion to amend after Dr. Vergnault’s deposition. It is of no moment that defendant tried to “resolve this issue” with plaintiffs before it filed its motion. RB at 10. Even with consent, there is no guarantee that defendant’s request to amend would have been granted.

2. Indefiniteness and Enablement

The Court also finds that defendant did not act diligently to discover that its proposed indefiniteness and lack of enablement contentions were appropriate. In evaluating defendant’s diligence the Court has to consider the following general principles. The burden to establish diligence rests with the moving party. O2 Micro, 467 F.3d at 1366. The good cause showing requires diligence throughout the discovery process. See West v. Jewelry Innovations, Inc., C.A. No. 07-1812, 2008 WL 4532558, at *2 (N.D. Cal. Oct. 8, 2008). Thus, even if a party timely moves to amend after discovering new information this does not necessarily establish diligence and good cause. Id. at *4 (“Although Benchmark’s motion to add the Rein patent to its preliminarily invalidity contentions was timely filed, that fact alone does not establish diligence. . . . Benchmark cannot rely solely on the timeliness of its motion[.]”). In addition, blanket assertions that a party acted “diligently” does not carry the day. Instead, a party must provide more information

such as when it began its inquiries and/or how it inquired. Id. at *3.

Here defendant rests its diligence argument on the fact that it did not learn about alleged key new information until Dr. Vergnault's deposition on November 19 and 20, 2014. Nevertheless, defendant does not explain why it waited so long to take this key deposition. Surely defendant knew or should have known about Dr. Vergnault's importance at the inception of the case. Given that the Rule 16 Conference was held on January 7, 2014, the January 13, 2014 Scheduling Order set a December 19, 2014 fact discovery deadline, and defendant waited until November 19 and 20, 2014, to take Dr. Vergnault's deposition, the Court finds that defendant did not exercise due diligence to discover that its amendments were appropriate. Defendant could have and should have anticipated that Dr. Vergnault's deposition would reveal potentially important information. This being the case defendant should have scheduled its depositions accordingly. Had defendant scheduled Dr. Vergnault's deposition earlier, plaintiffs would not be faced with a material amendment after the Markman ruling, after all fact discovery has been completed, and on the eve of the production of expert reports.

This Court is not alone in holding parties' "feet to the fire" when it comes to deposition scheduling. See Paice LLC v. Hyundai Motor Company, C.A. No. 12-0499, 2014 WL 5581045, at *8

(D. Md. Oct. 29, 2014) (affirming Magistrate Judge's Order holding that defendants did not exercise due diligence to amend their contentions when they offered no explanation for why they did not attempt to depose a key witness earlier); Symantec Corp. v. Acronis Corp., C.A. No. 11-5310, 2013 WL 5368053, at *7 (N.D. Ca. Sept. 25, 2013) (defendant's lack of diligence is evidenced by the fact that it waited until the week before the close of fact discovery to take the deposition that put it on notice of the need to amend its invalidity contentions); Nomadix, Inc. v. Hewlett-Packard Co., C.A. No. 09-08441, 2012 WL 994324, at *3 (C.D. Ca. March 22, 2012) (denying defendants' motion to amend their invalidity contentions because, inter alia, they did not explain why they did not depose a particular witness sooner, rather than waiting until late in discovery); C&C Jewelry Manufacturing, Inc. v. West, C.A. No. 09-1303, 2011 WL 835821, at *3 (N.D. Ca. March 4, 2011) (plaintiff did not exercise diligence to amend its validity contentions since it failed to explain why it waited so long to schedule a deposition; also noting that since plaintiff discovered new materials "so late in the litigation, it set the instant motion [to amend] for hearing after the close of fact discovery."). These holdings are not surprising since patent rules are "designed to require parties to crystallize their theories of the case early in the litigation and to adhere to those theories once they have been

disclosed.” O2 Micro, 467 F.3d at 1366 n.12 (citation and quotation omitted).

The Court’s ruling should not be read to bar all amendments after an inventor’s deposition is taken late in the case. Circumstances may exist where it is necessary to take a late deposition such as when the witness is unavailable or ill, or when it is unreasonably difficult to serve a non-party witness. This did not occur here. Dr. Vergnault is employed by plaintiff Jagotec and could have easily been deposed earlier in the case. Defendant has not posited a justifiable reason why Dr. Vergnault’s deposition was taken so late.⁵ If the Court permitted the amendment here it could lead to instances where parties strategically delay key depositions until the last minute to give their adversary as little time as possible to oppose their contentions. This type of gamesmanship is to be avoided. Permitting defendant’s late amendment would be inconsistent with the goal of the patent rules to prevent a “shifting sands” defense. This is the scenario the patent rules were designed to prevent. See Nova Measuring Instruments Ltd. v. Nanometrics, Inc., 417 F. Supp. 2d 1121, 1122-23 (N.D. Cal. 2006) (“The rules

⁵ The Court does not accept the notion that inventors’ depositions have to be taken after the Markman ruling. This scheduling would wreak havoc with the Court’s efforts to effectively and efficiently manage patent cases. It is not unheard of for Markman rulings to be issued after fact discovery deadlines expire. If parties routinely waited until after the Markman ruling is issued to take key depositions, it would result in inordinate delay in the resolution of patent cases. To be sure, however, circumstances may exist where it is appropriate to permit limited discovery after a Markman ruling.

are designed to require parties to crystallize their theories of the case early in the litigation and to adhere to these theories once they have been disclosed.").

Perhaps if Dr. Vergnault had been unavailable and if the Markman ruling was unexpected defendant would have a better argument. This is not the case here. Plaintiffs could have easily made Dr. Vergnault available for deposition early in the case. Further, defendant was on notice of plaintiffs' claim construction as to the term "insoluble or poorly water soluble hydrophobic material" that the Court eventually adopted. Defendant could have raised its Section 112 defense at the Markman hearing. Moreover, defendant had the opportunity to question Dr. Vergnault about plaintiffs' construction early in the case if it exercised due diligence. Thus, the Court could have considered defendant's arguments without the necessity of an "eleventh hour" amendment. Nautilus Neurosciences, Inc. v. Wockhardt USA, LLC, C.A. No. 11-1997 (ES/SCM), 2013 WL 7901901, at *7 (D.N.J. Jan. 23, 2013) ("Diligence does not exist where Defendants uncover the basis of an invalidity defense during the claim construction process if they could have done so prior to filing their invalidity contentions.").⁶

⁶ Defendant has also not made a convincing argument that the substance of Dr. Vergnault's testimony could not have been learned from documents produced in the case or from consulting with its own experts.

The Court understands that L. Pat. R. 3.7 is not a straightjacket into which litigants are locked from the moment their contentions are served. TFH Publications, Inc. v. Doscocil Mfg. Co., Inc., 705 F. Supp. 2d 361, 366 (D.N.J. 2010), quoting Comcast Cable Communications Corp. v. Finisar Corp., C.A. No. 06-4206, 2007 WL 716131, at *2 (N.D. Cal. March 2, 2007). The applicable patent rules unquestionably permit a modest degree of flexibility with regard to amendments of contentions, at least near the outset of a case. Id.; see also Int'l Dev. LLC v. Richmond, C.A. No. 09-2495 (GEB), 2011 WL 149859, at *3 (D.N.J. Jan. 18, 2011); AstraZeneca AB v. Hanmi USA Inc., C.A. No. 11-760 (JAP), 2011 WL 5526009, at *4 (D.N.J. Nov. 14, 2011). In this case, however, plaintiffs' lack of diligence, combined with the late stage of the case, warrants the denial of defendant's motion.

Defendant cites to L. Pat. R. 3.7 which gives as an example of good cause a claim construction by the Court different from that proposed by the party seeking amendment. However, a Markman ruling is not a "free pass" to grant motions to amend contentions. The moving party still has to show that it acted diligently to determine that an amendment was necessary which defendant has not done here.⁷

⁷ Further, for the reasons discussed infra, defendants did not timely move to amend its contentions after Dr. Vergnault's deposition. As noted, given the late stage of the case and the December 19, 2014 fact discovery deadline, and

Ordinarily the Court will only consider prejudice to the non-moving party if the moving party has made the requisite showing of diligence. Merck Sharpe & Dohne Corp. v. Sandoz, Inc., C.A. No. 12-3289 (PGS/LHG), 2014 WL 997532, at *4 (D.N.J. Jan. 6, 2014). The Court notes, however, that plaintiffs have made a credible argument they will be prejudiced if defendant's amendment is granted. Plaintiffs may be required to take more discovery and supplement their planned expert case. Aside from the additional cost, the ultimate resolution of the case could be delayed.

Conclusion

In sum, for the reasons discussed herein, the Court finds that defendant has not shown good cause to amend its contentions. Defendant was not diligent in determining that an amendment was appropriate and defendant did not timely move to amend its contentions. Defendant's motion is denied.

ORDER

Accordingly, and for all the foregoing reasons,

the looming expert deadlines, defendant should not have waited until six (6) weeks after Dr. Vergnault's deposition to file the instant motion.

IT IS HEREBY ORDERED this 24th day of February, 2015, that defendant's Motion for Leave to Amend its Invalidity Contentions is DENIED.

s/Joel Schneider
JOEL SCHNEIDER
United States Magistrate Judge

EXHIBIT G

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

PROMETHEUS LABORATORIES INC., .
Plaintiff, .
vs. . Case Nos. 11-cv-01241,
11-230
ROXANE LABORATORIES, INC., . August 6, 2012
Defendant. .

TRANSCRIPT OF RECORDED OPINION
BY THE HONORABLE PATTY SHWARTZ
UNITED STATES MAGISTRATE JUDGE

APPEARANCES:

For the Plaintiff: No one was present

For the Defendant: No one was present

Audio Operator:

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1 (Commencement of proceedings)

2

3 THE COURT: This matter has come before the Court
4 by way of defendant Roxane Laboratory Inc.'s request for
5 leave to add invalidity contentions regarding plaintiff
6 Prometheus Laboratory Inc.'s U.S. Patent Number 6,175,014,
7 hereinafter the "'014 Patent," and plaintiff's request to
8 strike the affirmative expert report of Bruce Ganem. For the
9 reasons set forth herein, the request for leave to add
10 invalidity contentions is denied and the request to strike
11 the Ganem report is granted in part and denied in part.

12 By way of background, this case concerns patents
13 for the methods of making, preparing, using and administering
14 alosetron hydrochloride to treat irritable bowel syndrome.
15 See the Amended Complaint at paragraphs 22 to 23, ECF
16 Number 67.

17 On January 16, 2001, the U.S. Patent and Trademark
18 Office issued the '014 Patent, entitled "Process For the
19 Preparation of Lactam Derivatives." Amended Complaint at
20 paragraph 23. The claims of the '014 Patent cover, among
21 other things, novel processes for making and preparing the
22 compound alosetron hydrochloride. Id.

23 On September 4, 2011, the U.S. Patent and Trademark
24 Office issued U.S. Patent Number 6,248,770, hereinafter, the
25 "'770 Patent," entitled "Medicaments For the Treatment of

1 Non-Constipated Female Irritable Bowel Syndrome." Id. at 22.

2 On March 4, 2011, plaintiff filed a complaint
3 against defendant for infringement of the '770 Patent. See
4 the Complaint, ECF Number 1 at paragraph 15.

5 On March 30, 2011, plaintiff filed an answer to
6 that complaint. ECF Number 7.

7 On November 14, 2011, the Court granted plaintiff's
8 request to add a claim of direct infringement of the '014
9 Patent. ECF Number 65.

10 On November 18, 2011, plaintiff filed its first
11 amended complaint against defendant, as well as Cipla Ltd.
12 and Byron Chemical Company Inc.

13 And on December 5, 2011, defendant filed its answer
14 to plaintiff's amended complaint. ECF Number 72.

15 On March 9, 2012, the parties filed Markman opening
16 briefs as to the '014 Patent. ECF Numbers 117 and 118.

17 On April 9, 2012, the parties filed Markman
18 response briefs as to the '014 Patent. ECF Numbers 138 and
19 139.

20 By way of joint letter dated February 15, 2012,
21 defendant sought leave to amend its invalidity contentions as
22 to the '770 Patent to add a contention that the '770 Patent
23 was invalid for lack of written description under 35 U.S.C.
24 § 112, and that the reexamined claims were invalid under 35
25 U.S.C. § 305 for improper examination. ECF Number 49. The

1 Court denied the request on March 12, 2012. ECF Number 120.
2 The defendant appealed this order on March 27, 2012. ECF
3 Number 131. And on June 4, 2012, Judge Hochberg denied the
4 request to amend the invalidity contentions and affirmed the
5 March 12, 2012, order; ECF Number 158.

6 On March 23, 2012, the Court convened a telephone
7 conference during which defendant raised for the first time
8 its view that if the Court adopted plaintiff's proposed claim
9 constructions, that the '014 Patent would be invalid.
10 Defendant asserted, however, that it believed it would be
11 premature to amend its invalidity contentions at that time
12 because the Court had not yet construed the claims. ECF
13 Number 134.

14 On March 27, 2012, defendant deposed plaintiff's
15 claim construction expert, Dr. Gorkal [phonetic]. ECF
16 Number 169 at 4.

17 On June 25, 2012, defendant served the Ganem
18 report. Id.

19 On June 27, 2012, the Court convened a telephone
20 conference during which the defendant again raised the
21 possibility it would seek to amend its invalidity contentions
22 based upon plaintiff's proposed claim construction. ECF
23 Number 168.

24 By way of joint letter dated July 23, 2012,
25 defendant sought leave to amend its invalidity contentions as

1 to the '014 Patent, based on plaintiff's proposed claim
2 constructions. ECF Number 169.

3 Defendant seeks leave to add these constructions,
4 claiming they are contingent on the Court's adoption of
5 plaintiff's proposed constructions for certain '014 Patent
6 claim terms. And defendant argues that should the Court
7 adopt such constructions, it should be permitted to assert
8 invalidity defenses as to the '014 Patent. Defendant argues
9 that it has good cause to amend its contentions because: (1)
10 under L. Pat. R. 3.7(a), a party has good cause to amend
11 contentions when a "claim construction by the court differ[s]
12 from that proposed by a party seeking amendment; and (2)
13 plaintiff's proposed constructions markedly differ from and
14 result in claims with far broader scope than the
15 constructions that defendant proposed. Specifically,
16 defendant contends that under plaintiff's proposed
17 constructions, the asserted '014 Patent claims are invalid
18 because they (1) lack written description under 35 U.S.C.
19 § 112, and (2) are anticipated under § 102 and are obvious
20 under 35 U.S.C. § 103.

21 Defendant argues that it has good cause to add the
22 proposed defenses because it exercised diligence in
23 developing those theories. Defendant argues it did not have
24 enough information to prepare and submit invalidity
25 contentions on February 7, 2012, when it received plaintiff's

1 proposed claim constructions regarding the '014 Patent,
2 because: (1) plaintiff's proposed constructions on their face
3 do not convey how broad plaintiff believes its proposed
4 construction makes the claims of the '014 Patent; and (2)
5 defendant only learned of the full impact of plaintiff's
6 proposed constructions on the scope of the claims after
7 taking the deposition of plaintiff's claim construction
8 expert Dr. Gorkal on March 27, 2012, and upon receiving
9 plaintiff's amended disclosure of asserted claims and
10 infringement contentions on March 1, 2012, and plaintiff's
11 Markman's briefs on March 9 and April 9, 2012. Defendant
12 also argues that it required its expert, Dr. Ganem's
13 expertise and knowledge to develop this proposed defense, and
14 his report was not disclosed until June 25, 2012.

15 Defendant argues its proposed contingent invalidity
16 contentions are not untimely, as under L. Pat. R. 3.7(a) a
17 party may amend its contentions when a "claim construction by
18 the court differ[s] from that proposed by the party seeking
19 amendment." Defendant argues that its proposed contentions
20 appear to be premature but is raising them before the court
21 makes a Markman decision based on discussion with the
22 plaintiff and the court during the June 27, 2012, telephone
23 conference. Defendant argues it was not aware of its
24 proposed invalidity contentions at the time plaintiff was
25 granted leave to add the '014 Patent to the case because

1 defendant's original contentions were due on December 22,
2 2011, before (1) defendant learned of plaintiff's proposed
3 constructions or (2) defendant could develop contentions
4 based on plaintiff's proposed constructions. Defendant
5 argues its proposed contentions would neither delay the
6 resolution of the case nor prejudice plaintiff because (1)
7 defendant's "written description" defense presents the same
8 issues raised in the parties' Markman briefing; (2) no fact
9 discovery is necessary to support or rebut these contentions;
10 and (3) plaintiff has time to respond to develop contentions
11 in opposition to defendant's proposed contentions. Defendant
12 argues that it provided plaintiff notice of its proposed
13 contentions by (1) serving it the June 25, 2012, affirmative
14 expert report of Bruce Ganem, which disclose defendant's
15 detailed basis for why it believes that under plaintiff's
16 claim constructions, the asserted '014 claims are invalid;
17 (2) serving its opening Markman brief as well as its
18 responsive Markman brief; and (3) discussing amending its
19 invalidity contentions during the March 23, 2012, telephone
20 conference.

21 Defendant further argues that it is in the public
22 interest for the Court to consider its contingent invalidity
23 defenses if the Court adopts plaintiff's proposed claim
24 constructions because to allow the plaintiff to block new
25 invalidity contentions based on unduly broad claim

1 constructions would give free license to a patentee to argue
2 for the broadest possible constructions without regard to how
3 the prior art would impact the validity of the claims in view
4 of such broad constructions.

5 In opposition, plaintiff argues that defendant
6 lacks good cause to amend its proposed invalidity contentions
7 because: (1) the local patent rules do not contemplate
8 allowing amendments to contentions based on proposed claim
9 constructions of an adverse party that the court has yet to
10 address; (2) defendant should have been aware of the
11 information necessary to assert its invalidity defenses since
12 plaintiff sought leave to add the '014 patent to the case on
13 September 23, 2011, as the information necessary to formulate
14 the defenses is found in the '014 Patent itself and its
15 prosecution history; and (3) defendant fails to explain how
16 plaintiff's proposed constructions of the asserted claims
17 prevented defendant from asserting its defenses earlier or
18 how they arise solely under plaintiff's interpretation of the
19 claims.

20 Plaintiff further argues that defendant was not
21 diligent in seeking its amendments as: (1) defendant fails to
22 identify any testimony given by Dr. Gorkal or statements made
23 in plaintiff's contentions or Markman briefing that broaden
24 plaintiff's proposed claim construction or otherwise justify
25 defendant's delay; (2) defendant's claim that it put

1 plaintiff on notice of its new defenses in the Markman
2 briefing demonstrates defendant had sufficient information to
3 articulate invalidity defenses in early March 2012; and (3)
4 defendant could have consulted an expert when the amended
5 complaint was filed.

6 Plaintiff argues that defendant's request to amend
7 is untimely because: (1) defendant had all the information
8 necessary to assert its invalidity defenses nearly three
9 months before the Court's December 22, 2011, deadline for
10 serving invalidity contentions related to the '014 Patent;
11 (2) even if the invalidity defenses arise only under
12 plaintiff's proposed constructions of the '014 Patent claims,
13 defendant had been on notice of potential invalidity arising
14 from plaintiff's proposed construction for at least five
15 months as plaintiff's proposed constructions to the '014
16 Patent claims were closed to defendant on February 7, 2012.

17 Plaintiff further argues that as defendant cannot
18 show it was diligent in seeking to add its invalidity
19 defenses, plaintiff need not show prejudice as a result of
20 the defendant's delay. Plaintiff further argues that
21 defendant's proposed amendments would be prejudicial as: (1)
22 defendant conducted discovery knowing it might assert an
23 invalidity defense, but plaintiff did not pursue certain fact
24 discovery in reliance on the absence of the invalidity
25 contentions defendant now seeks to add and on defendant's

1 statement it did plan on amending its contentions before the
2 Court construed the dispute claim terms; and (2) plaintiff
3 built its litigation strategy around defendant's original
4 contentions.

5 Plaintiff further argues that allowing defendant to
6 amend its invalidity contentions is not in the public
7 interests as it would allow defendant to circumvent the
8 disclosure requirements of the rules.

9 L. Pat. R. 3.7 of the local rules of the United
10 States District Court for the District of New Jersey which
11 governs amendments to invalidity contentions provides
12 "amendment of any contentions, disclosures or other documents
13 required to be filed or exchanged pursuant to these Local
14 Patent Rules may be made only by order of the court upon a
15 timely application and showing of good cause. The
16 application shall disclose whether parties consent or object.
17 Non-exhaustive examples of circumstances that may, absent
18 undue prejudice to the adverse party, support a finding of
19 good cause include: (a) a claim construction by the court
20 different from that proposed by the party seeking amendment;
21 (b) recent discovery of material prior art, despite earlier
22 diligent search; (c) recent discovery of non-public
23 information about accused instrumentality which was not
24 discovered despite diligent efforts before the service of
25 infringement contentions; (d) the disclosure of an

1 infringement contention by a Hatch-Waxman Act party asserting
2 infringement under L. Pat. R. 3.6(g) that requires responses
3 by the adverse party because it was not previously presented
4 or reasonably anticipated; and (e) consent by the parties in
5 interest to the amendment and a showing that it will not lead
6 to an enlargement of time or impact other schedule deadline.
7 The duty to supplement discovery responses under Fed. R. Civ.
8 P. 26(e) does not excuse the need to obtain leave of court to
9 amend contentions, disclosures or other documents required to
10 be filed or exchanged pursuant to these Local Patent Rules."
11 L. Pat. R. 3.7.

12 Thus, pursuant to Rule 3.7, the court may permit a
13 party to amend its invalidity contentions provided the
14 following three elements are established: (1) the moving
15 party makes a timely application to the court; (2) there is
16 good cause for the amendment; and (3) there is no undue
17 prejudice to the adverse party. See id.

18 Federal Circuit precedent governs the
19 interpretation of local patent rules because such issues are
20 "intimately involved in the substance of enforcement of the
21 patent right." O2 Micro International Ltd. v. Monolithic
22 Power Systems Inc., 467 F.3d 1355, 1364 (Fed. Cir. 2006)
23 (internal quotation marks and citations omitted). The patent
24 rules governing contentions are designed to encourage parties
25 to "provide early notice of their infringement and invalidity

1 contentions and to proceed with diligence in amending those
2 contentions when new information comes to light in the course
3 of discovery." Id. at 1365 to 66.

4 The local rules "seek to balance the right to
5 develop new information in discovery with the need for
6 certainty as to the legal theories." Id. at 1366. The local
7 patent rules require "parties to crystallize their theories
8 of the case early in the litigation." Id. at 1366 n.12
9 (internal quotation marks and citations omitted).

10 Amendments to infringement and invalidity
11 contentions are not granted as liberally as requests for
12 amendments to pleadings in part because "the philosophy
13 behind amending claim charts is decidedly conservative and
14 designed to prevent the 'shifting sands' approach" to a
15 party's contentions. King Pharmaceuticals v. Sandoz,
16 Civ. No. 08-5974, 2010 WL 2015258 at *4 (D.N.J. May 20, 2010)
17 (internal quotation marks and citations omitted); cf. Fed. R.
18 Civ. P. 15(a)(2).

19 New Jersey's local patent rules require the party
20 seeking to amend to demonstrate that it has made a showing of
21 "good cause." L. Pat. R. 3.7. Good cause "requires a
22 showing of diligence." O2 Micro, 367 F.3d at 1366. And the
23 "burden is on the movant to establish diligence rather than
24 on the opposing party to establish a lack of diligence." Id.
25 (Internal citations omitted).

1 The good cause showing "requires diligence
2 throughout the discovery process and that the moving party
3 not only must act promptly upon discovery of new
4 information] but also must establish that it was diligent in
5 its search..." West v. Jewelry Innovations Inc.,
6 Civ. No. 07-1812, 2008 WL 4532558 at *2 (N.D. Cal. October 8,
7 2008). As such, the Court "must address whether the party
8 was diligent in discovering the basis for the proposed
9 amendment." Id. at 2.

10 The local rule gives several non-exhaustive
11 examples of good cause, two of which focus on the moving
12 party's diligence in locating the newly discovered
13 information and its explanation for not including it in its
14 original contentions. L. Pat. R. 3.7. See O2 Micro, 467
15 F.3d at 1367; King Pharmaceuticals, 2010 WL 2015258 at *4.
16 According to Rule 3.7, examples of situations where good
17 cause may be found include: "(a) a claim construction by the
18 court different from that proposed by the party seeking
19 amendment; (b) recent discovery of material prior art despite
20 earlier diligence; and (c) recent discovery of non-public
21 information about the accused instrumentality which was not
22 discovered, despite diligent efforts, before the service of
23 the infringement contention ..." L. Pat. R. 3.7.

24 Although the local patent rule notes that "a claim
25 construction by the court different from that proposed by the

1 party seeking amendment," id., can be a circumstance that
2 merits a finding of good cause, this does not mean that
3 anytime a court adopts a claim construction different from
4 what a party proposed that that party may automatically amend
5 its invalidity contentions. Such a leap "would destroy the
6 effectiveness of the local rules in balancing the discovery
7 rights and responsibilities of the parties." Finisar Corp.
8 v. DirectTV Group Inc., 424 F. Supp. 2d 896, 900 to 901 (E.D.
9 Tex. 2006). Accordingly, defendant's argument that its
10 amendments are being made before claim construction and being
11 done in the event the court eventually adopts plaintiff's
12 proposed construction, does not end the inquiry. Indeed,
13 "parties who are on notice of the opposing party's claim
14 construction and do not prepare for the fact that the court
15 may adopt it, can be held accountable." Convolve Inc. v.
16 Compaq Computer Corp., Civ. No. 5141, 2006 WL 2527773 at *4
17 (S.D.N.Y. August 13, 2006).

18 As the court in Sinclair Intellectual Property
19 Consultants Inc. v. Matsushita Electronics Industry Company
20 Ltd., Civ. Nos. 04-1436, 06-404, 08-371, 2012 WL 1015993 at
21 *5 (D. Del. March 26, 2012), put it, "when claim construction
22 remains an open issue at the time the parties serve expert
23 reports and infringement contentions, the parties have an
24 obligation to prepare for the fact that the party may adopt
25 [the other party's] claim construction." (quoting Union

1 Carbide Chemicals and Plastics Technologies Corp., v. Shell
2 Oil Company, 270 F. Supp. 2d 519, 524 (D. Del. 2003). See
3 also Finisar, 424 F. Supp. 2d at 900 to -01. In Finisar, the
4 court stated that to allow an amendment when a party
5 "believes in good faith that the court's claim construction
6 ruling so requires ... is intended to allow a party to
7 respond to an unexpected claim construction by the court.
8 This does not mean that after every claim construction order,
9 new invalidity contentions may be filed."

10 The local rule here attempts to provide a means to
11 amend contentions to address an unexpected construction. To
12 interpret rule otherwise, would mean that a party could wait
13 until after the construction to take action, even though they
14 were fully equipped to act sooner. This would be
15 inconsistent with the rule's purpose, which is to solidify
16 all known positions. If a party knows of the adverse party's
17 construction, it will undoubtedly take steps to defeat the
18 construction and to ameliorate the impact of the construction
19 if adopted. Thus, if a party presents a claim construction
20 that if adopted would result in new invalidity or
21 infringement positions by an opposing party, the opposing
22 party has a duty to act diligently on such information and
23 make an application to amend. It would not be acting
24 diligently if it sat back, waited to see if the construction
25 was adopted, then sought to embrace another defense it was

1 aware it would adopt if its claim construction were rejected
2 and the adversary's was adopted.

3 Defendant, accordingly, had a duty to formulate any
4 invalidity defenses directed at plaintiff's proposed
5 constructions as soon as it received them and promptly seek
6 to amend contentions it wanted to have the ability to pursue.

7 By requiring such action, it ensures that all positions are
8 announced as soon as the information upon which the position
9 is based is known. Moreover, it ensures that a party who
10 seeks to argue for a broad construction is confronted with
11 the consequence of such a position, such as additional
12 invalidity challenges as soon as they are known.

13 Defendant admits receiving plaintiff's proposed
14 claim constructions on February 7, 2012, and those
15 constructions were filed with the Court on March 9, 2012.
16 See ECF Number 169 at 3. See also plaintiff's Markman brief,
17 ECF 117.

18 By February 7, 2012, defendant possessed all the
19 information necessary to formulate invalidity contentions
20 under plaintiff's proposed claim constructions. Not only was
21 defendant on notice of plaintiff's proposed constructions,
22 but defendant demonstrated under the circumstances awareness
23 of invalidity issues raised by the constructions in its
24 Markman briefs and during the March 23, 2012, telephone
25 conference. Defendant argued in its March 9, 2012, Markman

1 brief that plaintiff's proposed claim construction would
2 render the '014 Patent "invalid for failing to comply with
3 the written description requirement of 35 U.S.C. § 112." See
4 the defendant's '014 Markman brief, ECF 118 at 12, note 9.
5 Moreover, during the March 23, 2012, telephone conference,
6 defendant stated, "when we reviewed Prometheus's recently --
7 recently filed opening claim construction brief for the '014
8 Patent and the arguments set forth therein, it became evident
9 that were the Court to construe a particular claim term
10 according to Prometheus's proposed construction, the '014
11 Patent may be invalid for failing to comply with the written
12 description requirement of 35 U.S.C. 112." See the Telephone
13 Conference at pages 21, line 17 to page 22, line 9;
14 and page 22 line 15 to line 23; and page 23, line 21 to
15 page 24, line 1.

16 Thus, not only could defendant have formulated
17 invalidity defenses soon after February 7, 2012, it evidently
18 did so.

19 Even as to invalidity defenses, the defendant may
20 not have articulated in its Markman briefing or during a
21 conference with the Court, defendant cannot justify its delay
22 in formulating contentions based on plaintiff's proposed
23 contentions. Although defendant asserts that it required
24 Dr. Ganem's expertise in chemistry and chemical synthesis to
25 understand the impact of plaintiff's proposed claim

1 constructions to understand how prior art disclosures relate
2 to patent claims under plaintiff's proposed constructions and
3 to use that information to develop its defenses, this is
4 undermined by defendant's ability to make at least certain
5 arguments about invalidity months before it disclosed
6 Dr. Ganem's report on June 25, 2012. Moreover, the amount of
7 time that defendant waited to file its amended invalidity
8 contentions exceeded the acceptable time frame to warrant a
9 finding of diligence. "While a [party] may require time to
10 digest and marshal [the] evidence, develop a new theory, and
11 then chronicle the complete theory in contentions, this
12 period must be reasonable." Realtime Data LLC v. Packeteer
13 Inc., Civ. No. 08-144, 2009 WL 2590101 at *4 (E.D. Tex.
14 August 18, 2009) (quoting O2 Micro, 467 F.3d at 1366
15 (internal quotation marks omitted)).

16 Here, the defendant had the proposed construction
17 since February 2012 and provided no explanation why they were
18 not promptly shared with their expert, particularly where
19 within four weeks of receipt, the defendant already concluded
20 that the constructions, if adopted, presented plaintiff with
21 validity problems. Further, "the Federal Circuit has held
22 that generalized statements by a party attributing its delay
23 in moving to amend infringement contentions to its need to
24 consult with experts, carry no weight in the good cause
25 analysis." Volumetrics Medical Imaging LLC v. Toshiba

1 America Medical Systems Inc., Civ. No. 05-955, 2011 WL
2 2359061 at *16 n.21 (M.D.N.C. June 9, 2011) (citing O2 Micro,
3 467 F.3d at 1367)). Courts may deny a request to amend where
4 a party fails to specifically point to an issue that
5 necessitated the delay. O2 Micro, 467 F.3d at 1367;
6 Realtime, 2009 WL 2590101 at *4.

7 Although defendant claims that Dr. Ganem's
8 expertise is necessary, it fails to identify the testimony in
9 Dr. Gorkal's deposition or in plaintiff's contentions or in
10 plaintiff's Markman brief that Dr. Ganem need months to
11 analyze. As previously discussed, defendant demonstrated its
12 view that plaintiff's claim construction rendered the '014
13 Patent invalid in defendant's March 9, 2012, opening Markman
14 brief; during the March 23, 2012, telephone conference; and
15 in defendant's April 9, 2012, responsive Markman brief.
16 Accordingly, it is unclear why defendant needed Dr. Ganem's
17 expertise to seek to add invalidity contentions it had
18 sufficient information to formulate in 2012 or why it took
19 until July 2, 2012, to serve the proposed invalidity
20 contentions on plaintiff. Thus, defendant has failed to show
21 good cause and diligence and, hence, this element is not met.

22 New Jersey's local patent rules also require the
23 party seeking leave to amend to demonstrate it made a timely
24 application. L. Pat. R. 3.7. The Federal Circuit has
25 emphasized the importance of this element, recognizing that

1 "if the parties were not required to amend their contentions
2 promptly after discovering new information, the contentions
3 requirement would be virtually meaningless as a mechanism for
4 shaping the conduct of discovery and trial preparation." O2
5 Micro, 467 F.3d at 1666.

6 Here, defendant sought to amend its proposed
7 contingent invalidity contentions before the Court construed
8 the claims at issue. Yet, as previously discussed,
9 defendant's argument that the proposed contentions were
10 submitted before claim construction, does not end the
11 inquiry. In determining whether defendant's application was
12 timely, the Court must look to the period of time between
13 the defendant learned of the basis of its amendment and the
14 time it filed its application. Defendant's proposed
15 contingent invalidity contentions were filed five months
16 after plaintiff's proposed claim construction of the '014
17 patent claims were disclosed on February 7, 2012.
18 Additionally, as previously discussed in its own March 9,
19 2012, Markman opening brief, defendant argued that
20 plaintiff's proposed claim construction would render the '014
21 Patent invalid for failing to comply with the written
22 description requirement of 35 U.S.C. § 112. See the
23 defendant's Markman brief at 12, note 9. Defendant also
24 demonstrated its knowledges of the allegedly problematic
25 nature of plaintiff's claim constructions in the March 23,

1 2012, telephone conference. See the Telephone Conference
2 Transcript at 21, lines 17 to page 22, line 9; page 22,
3 line 15 to 23; page 23, line 21 through page 24, line 1.
4 Defendant again raised invalidity issues in its April 9, 20,
5 responsive Markman brief, in which it noted that the proposed
6 construction so broadened the claims of the '014 Patent that
7 they are rendered invalid for lack of written description.
8 See the defendant's Markman responsive brief at 6, note 4.

9 Defendant nonetheless waited until July 2, 2012,
10 five months after receiving the proposed claim constructions
11 and almost four months after receiving plaintiff's Markman
12 brief, to file its request to amend. Thus, as defendant
13 chose to wait months before filing a request to amend its
14 invalidity contentions, its request to do so fails to meet
15 the local patent rules timely application requirement. See
16 O2 Micro, 467 F.3d at 1367.

17 Therefore, for this additional reason, the request
18 is denied.

19 Finally, the Court need only consider undue
20 prejudice if the moving party has timely moved and made the
21 requisite showing of good cause. O2 Micro, 467 F.3d at 1368.
22 See also Acer Inc. v. Technological Properties Ltd., Civ.
23 Nos. 08-877; 08-882; 08-5398, 2011 WL 1838768 at *2 (N.D.
24 Cal. May 13, 2011); Sunpower Corp. Systems v. Sunlink Corp.,
25 Civ. No. 08-2807, 2009 WL 1657987 at *1 (N.D. Cal. June 12,

1 2009) (citing O2 Micro, 467 F.3d at 1368)).

2 Because the defendant has not shown it acted with
3 diligence, the Court is not obligated to consider whether the
4 amendment would unduly prejudice plaintiff. Nonetheless, the
5 Court notes that an amendment at this stage would unduly
6 prejudice plaintiff. See Quantum Corp. v. Riverbed
7 Technologies Inc., Civ. No. 07-4161, 2008 WL 2783227 at *1
8 (N.D. Cal. July 15, 2008).

9 Here, claim construction briefing is completed,
10 fact discovery is closed, Markman expert depositions have
11 been completed. In addition, affirmative expert reports were
12 disclosed by June 25, 2012, and responsive reports were due
13 to be disclosed on August 3, 2012. ECF Number 167.

14 To grant leave to add invalidity contentions at
15 this stage would cause substantial prejudice to the plaintiff
16 as there is no longer an opportunity to conduct discovery
17 implicated by them. The stage of the proceedings and
18 prejudice to plaintiff further supports denial of leave to
19 assert the invalidity contentions.

20 Plaintiff also seeks to strike portions of the
21 Ganem report, arguing "its sole purpose ... is to support
22 Roxane's improper and belated invalidity contentions." To
23 the extent and only to the extent the Ganem report discusses
24 the basis for invalidity contentions regarding the '014
25 Patent, plaintiff [*sic*] seeks to but is not permitted to add,

1 the report would not be relevant, because it is not likely to
2 lead to the discovery of admissible evidence, as the defenses
3 addressed may not be added and will not be the subject of
4 trial testimony. The Court makes no ruling concerning any
5 other aspect of the report.

6 For all of these reasons, the defendant's request
7 for leave to add invalidity contentions is denied.

8 It is further ordered that the plaintiff's request
9 to strike Dr. Ganem's report is granted in part only to the
10 extent the report discusses the basis for the invalidity
11 contentions regarding the '014 Patent that defendant is
12 precluded from adding, and denied in part to the extent the
13 report discusses other matters.

14 A form of Order consistent with this Opinion will
15 be issued.

16 (Conclusion of proceedings)
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Certification

I, SARA L. KERN, Transcriptionist, do hereby certify that the 24 pages contained herein constitute a full, true, and accurate transcript from the official electronic recording of the proceedings had in the above-entitled matter; that research was performed on the spelling of proper names and utilizing the information provided, but that in many cases the spellings were educated guesses; that the transcript was prepared by me or under my direction and was done to the best of my skill and ability.

I further certify that I am in no way related to any of the parties hereto nor am I in any way interested in the outcome hereof.

s/ *Sara L. Kern*

August 9, 2012

Signature of Approved Transcriber

Date

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